
The Impact of a change in diagnostic test method for STEC infection

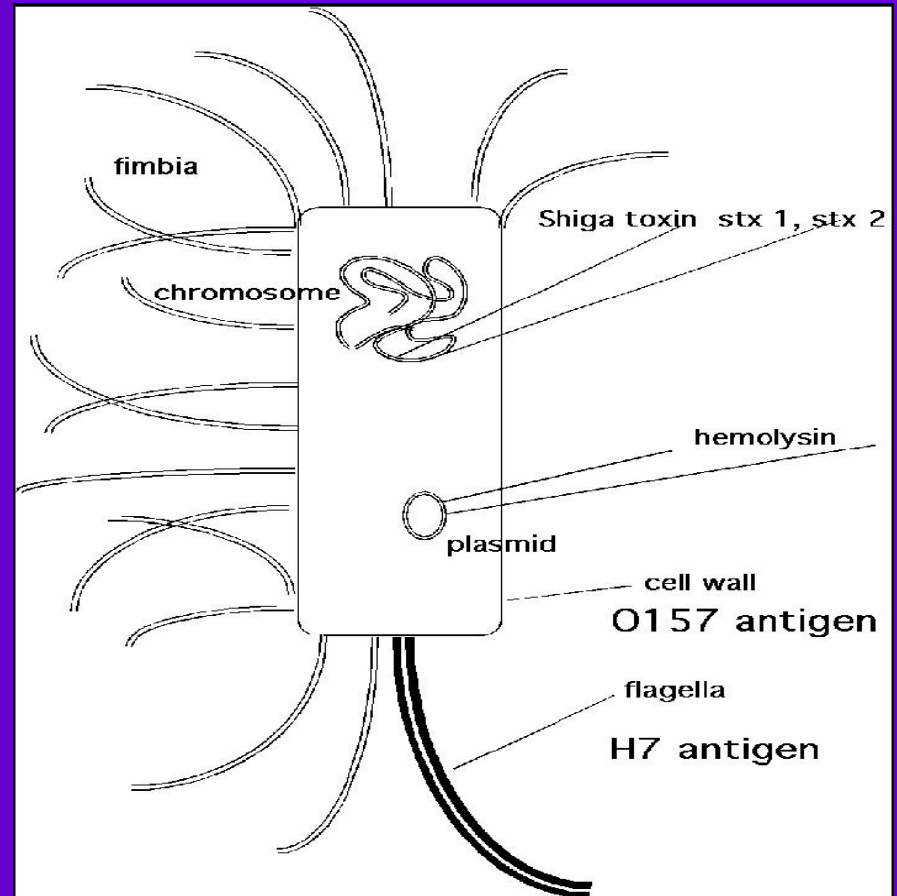
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Background: E. coli

- Six groups with different virulence traits
- Enterohemorrhagic E. coli (EHEC)
 - produce **shiga-toxins**
 - **responsible** for bloody diarrhea, hemolytic uremic syndrome (HUS)
 - **transmission**: food, water, person-to-person
 - serotype O157:H7 most common
 - **serotype** non-O157 also prevalent



Background: FoodNet

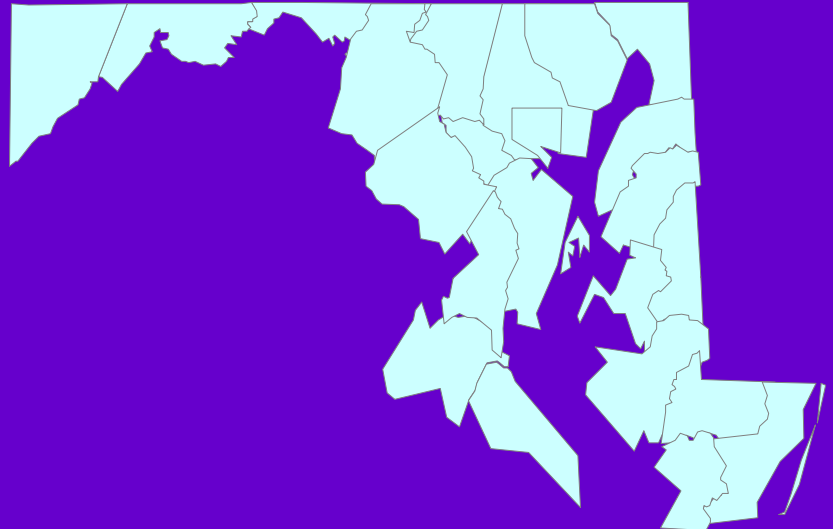
- CDC's Foodborne Active Surveillance Network
- **goal**: assess burden of foodborne disease
- started 1996
- participation of 10 states
- monitors 9 foodborne disease causing organisms
- all cases **laboratory-confirmed**



<http://www.cdc.gov/foodnet/#highlights>

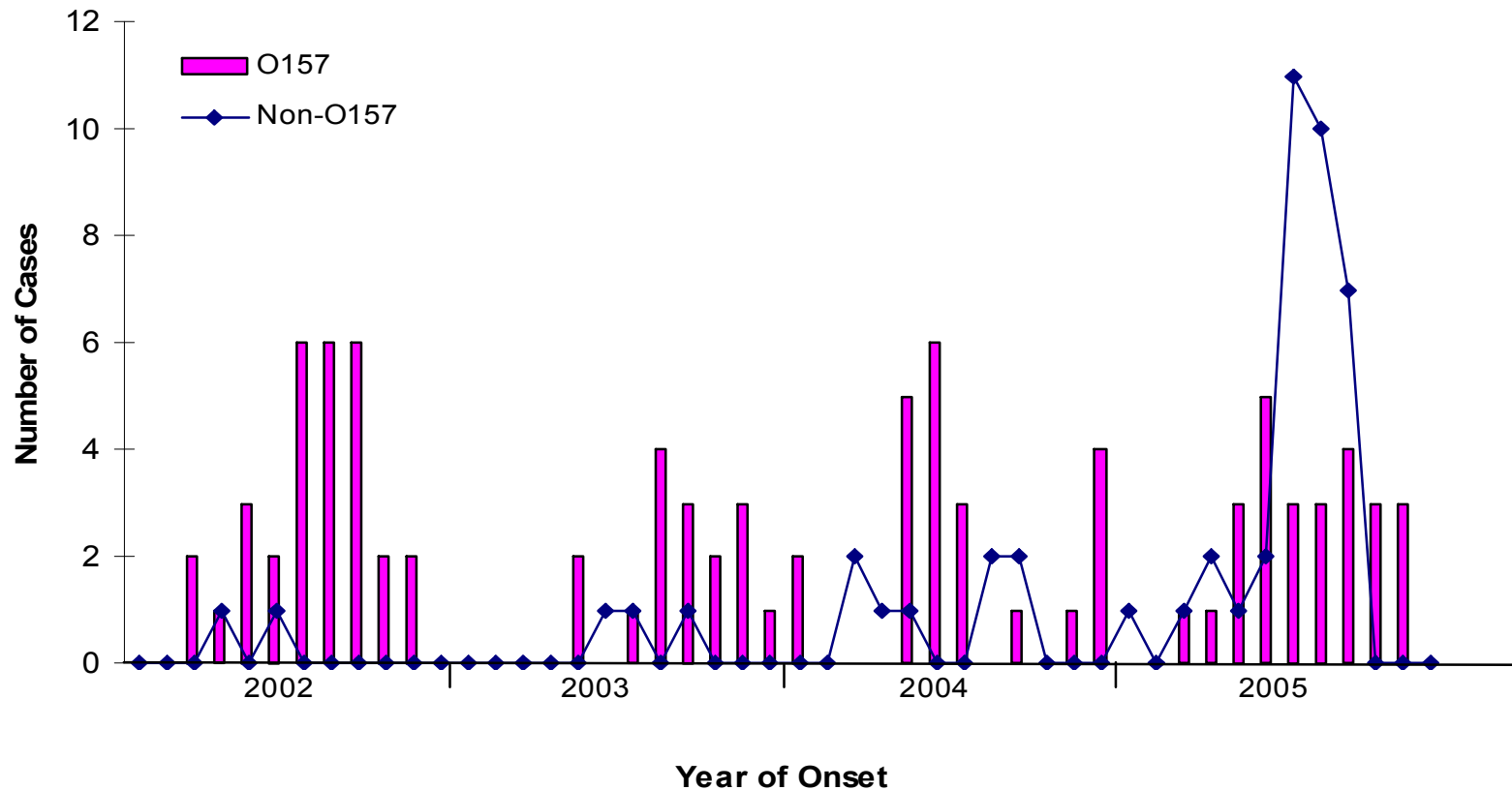
Background: FoodNet-Maryland

- Maryland
 - statewide participant of FoodNet
 - ~ 20-30 cases of O157 from 2002-05
 - 2-8 cases of non-O157 from 2002-04
 - 35 cases of non-O157 in 2005



Background: FoodNet-Maryland

Number of STEC cases by year for 2002-05 in Maryland, separately by serotype, non-O157 and O157

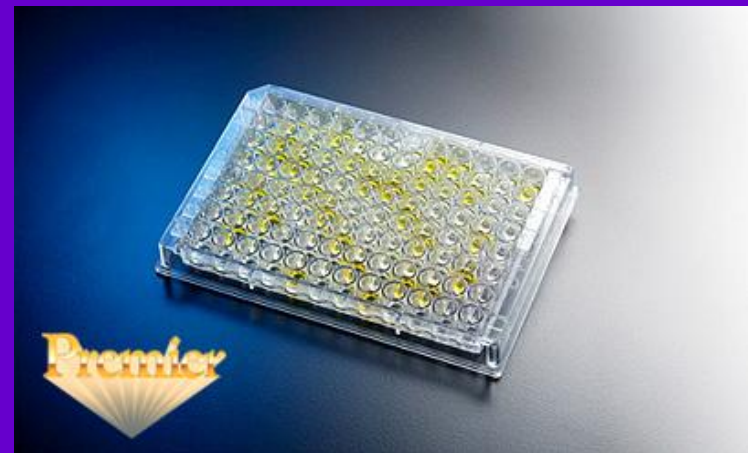


Background: FoodNet-Maryland

- Maryland
 - 50 clinical laboratories in Maryland
 - change of assay method by LabCorp in 2005

Background: Laboratory testing

- LabCorp
 - Sorbitol-MacConkey (SMAC) agar
 - before June 2005
 - 50% sensitivity for O157
 - 23.5% sensitivity for all EHEC
 - ELISA
 - after June 2005
 - 82.4% sensitivity for all EHEC



Research Question

Can the rise in STEC non-0157 cases in 2005 in Maryland be explained by the new lab assay implemented by LabCorp?

Methods: Study Design

- Cross-sectional study, years 2002-05
- **Inclusion** criteria:
 - All lab-confirmed STEC cases from Maryland
- **Exclusion** criteria:
 - Lab-confirmed STEC case but no serotype identified
 - 6 such cases total
- **Case**:
 - non-O157 infections
- **Comparison**:
 - O157 infections

Methods: Analysis

- **Outcome:** Risk of non-O157 infection
- **Exposure:** new lab test (ELISA –vs- SMAC)
- Logistic regression with adjustment for age

Results: Baseline Characteristics

Characteristic	0157	Non-0157	P Value
No. of cases	94	48	
Hospitalization (%)	34 (36.2)*	9 (18.7)	0.034
Gender (%)			1
Men	48 (51.1)	24 (50)	
Women	46 (48.9)	24 (50)	
Age (yrs)			
Mean (SD)‡	19.9 (20.1)	13.8 (17.6)	0.032
Interquartile range	5 - 36	2.5 - 17	
Age Groups (%), yrs			0.132
0-10	43 (45.7)	30 (62.5)	
11-17	15 (15.9)	6 (12.5)	
18-39	15 (15.9)	8 (16.7)	
40-59	17 (18.1)	2 (4.2)	
60+	4 (4.3)	2 (4.2)	
Median Income (%)			0.828
< 39,999	18 (19.1)	10 (20.8)	
40,000 - 49,999	14 (14.9)	5 (10.4)	
50,000 - 69,999	36 (38.3)	17 (35.4)	
70,000 +	26 (27.7)	16 (33.3)	
Race, No. (%)			0.046
White	72 (76.6)	29 (60.4)	
Black	13 (13.8)	7 (14.6)	
Other	9 (9.6)	12 (25)	
Ethnicity, No. (%)			0.037
Hispanic	3 (3.2)	7 (14.6)	
Not Hispanic	76 (80.8)	32 (66.7)	
Unknown	15 (15.9)	9 (18.7)	
Region, No. (%)			0.915
Greater Baltimore	53 (56.4)	25 (52.1)	
Capital	28 (29.8)	15 (31.2)	
Southern Maryland	3 (3.2)	2 (4.2)	
Western Maryland	1 (1.1)	0	
Eastern Shore	9 (9.6)	6 (12.5)	
Traveled (%)	12 (26.1)§	13 (34.2)§	0.477

- All cases ascertained 2002-05
- 48 cases of non-O157
- 94 cases of O157
- No differences Before ('02-'04) & After ('05) new test

Results: Analysis

Logistic regression model for Risk of non-O157 for years 2002-05 in Maryland: Univariate and Multivariate Analysis

Variable	Univariate analysis		Multivariate analysis	
	Odds ratio (95% CI)	P-Value	Adjusted OR (95% CI)	P-Value
Age (yrs)*				
11-17	0.57 (0.19-1.65)	0.302	0.46 (0.14-1.48)	0.189
18-39	0.76 (0.29-2.03)	0.590	0.56 (0.18-1.72)	0.315
40-59	0.17 (0.04-0.78)	0.023	0.29 (0.06-1.44)	0.130
60 +	0.72 (0.12-4.17)	0.711	0.67 (0.09-4.85)	0.693
Year of onset†				
2003	2.81 (0.42-18.6)	0.283		
2004	5.45 (1.05-28.24)	0.043		
2005	20.19 (4.42-92.19)	<0.001		
New test	8.12 (3.67-17.98)	<0.001	7.82 (3.40-17.98)	<0.001

* Reference category: age 0-10 years
† Reference category: year 2002

Conclusion: Limitations

- No information regarding **lab methods** for other 49 clinical labs
- **Selection bias**
 - underestimate of total cases in population
- No information on **food history**
- Small **sample size**
 - power

Conclusion: Evidence

1. **Higher Risk** associated with new lab test
 - univariate & multivariate analysis
2. **Increasing proportion** of overall case ascertainment by LabCorp
 - 10% reporting of cases, 2004
 - 30% reporting of cases, 2005
3. **No outbreaks** in 2005
 - ≥ 2 cases from common exposure
 - sudden spikes in temporal trends

Conclusion: Public Health Significance

So what?

- Interpretation of **time trends**
 - artifact or real rise in burden?
 - reason for differences across states?

What next?

- Better **assessment** of lab methods across all FoodNet sites
- **Standardization** of laboratory methods
 - equal sensitivity & specificity

Thank You!!!!

at DHMH:

Stephanie Mickelson, MHS

Gita Mirchandani, PhD, MPH

at JHSPH:

concentration classmates

all the epi & biostats TAs

